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| 10/529,397 | 03/28/2005 | Soren Flygenromg Christensen | CHRISTENSEN12 | 6716 |
| 1444 7590 04/10/2008 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303 | | | EXAMINER STEELE, AMBER D | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/529,397 | Applicant(s) CHRISTENSEN ET AL. | |
| | Examiner Amber D. Steele | Art Unit 1639 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) 1-31, 34-37, and 43-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32,33 and 38-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/28/05 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/27/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-102 are currently pending.

Claims 32-33 and 38-42 are currently under consideration.

Election/Restrictions

2. Applicant's election with traverse of Group II (claims 32-42) in the reply filed on January 17, 2008 is acknowledged. The traversal is on the ground(s) that the reference utilized to break the unity of invention (i.e. Frankel U.S. Patent 6,506,342) does not teach the specific size of the particles (i.e. diameter less than 30 microns) and the spectral encoding principle of Frankel is different from the spatial encoding principle of the presently claimed invention. In addition, applicants assert that the beads as claimed comprise particles. This is not found persuasive because while Frankel does not teach each and every limitation of the beads as presently claimed, Grotli et al. U.S. Patent 6,642,334 filed July 9, 2001 teaches resin beads (i.e. beads comprising particles) smaller than or around 500 μm and particles less than 30 μm (see specific citations in the rejection below; see also Figure 1). Thus, the common technical feature is known in the art.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-31 and 43-102 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 17, 2008.

Art Unit: 1639

3. Applicant's election with traverse of at least 10^2 beads in the reply filed on January 17, 2008 is acknowledged. The traversal is on the ground(s) that the generic claims are allowable and a composition comprising 10^{10} beads would read on all of present claims 32-37. This is not found persuasive because the generic claim is not allowable (please refer to the rejections below) and a composition comprising 100-999 beads would not read on claims 34-37.

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 34-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 17, 2008.

Priority

5. The present application claims status as a National Stage (i.e. 371) of PCT/DK03/00635 filed on September 26, 2003 which claims benefit of U.S. provisional applications 60/482,453 filed on June 26, 2003 and 60/413,771 filed September 27, 2002. In addition, the present application claims foreign priority to PA 2003 00969 filed June 26, 2003 and PA 2002 01444 filed September 27, 2002.

6. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

7. The information disclosure statement (IDS) submitted on March 27, 2006 is being considered by the examiner.

Drawings

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Schemes 1A, 1B, 2A, and 2B and Figures 5a and 5b are not described. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

9. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Figure 15. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one

Art Unit: 1639

figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

11. Claims 32-33 and 38-42 are objected to because of the following informalities: claim 32 incorporates limitations from withdrawn claim 1 (i.e. nonelected invention). Incorporation of the limitations of claim 1 into claim 32 is suggested. Appropriate correction is required.

12. Claim 41 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 32 reads “wherein essentially each bead” (i.e. essentially all) “is individually identifiable” and dependent claim 41 reads “wherein essentially all of said beads are individually identifiable”.

Claim Rejections – 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1639

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 38 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites the limitation “each beaded polymer matrix” in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 42 recites the limitation “the spatial positions of particles” in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Invention as Claimed

15. A composition comprising a plurality of different, spatially encoded beads wherein essentially each bead is individually identifiable and variations thereof.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1639

17. Claims 32 and 38-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Miranda et al. SPOCC-194, a New High Functional Group Density PEG-Based Resin for Solid-Phase Organic Synthesis *J. Comb. Chem.* 4: 523-529, 2002 (published August 10, 2002).

For present claims 32 and 41, Miranda et al. teach compositions of SPOCC₁₉₄ beads wherein each bead is individually identifiable (please refer to the entire reference particularly Figure 2).

For present claims 38-39, Miranda et al. teach compositions of SPOCC₁₉₄ beads (i.e. individually identifiable) with functionalized sites including photolabile linkers and nonaromatic linkers (please refer to the entire reference particularly Figures 2-3 and 5-7; page 526).

For present claim 40, Miranda et al. teach compositions of SPOCC₁₉₄ beads with linkers and peptides or glycopeptides attached (please refer to the entire reference particularly page 526; Figures 5-7).

For present claim 42, Miranda et al. teach three dimensional beads with particles (i.e. can be defined by x,y,z coordinates; please refer to the entire reference particularly Figure 2).

Therefore, the presently claimed invention is anticipated by the teachings of Miranda et al.

18. Claims 32 and 38-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Strathmann et al. Artificial biofilm model – a useful tool for biofilm research *Appl. Microbiol. Biotechnol.* 54: 231-237, 2000.

For present claims 32 and 41, Strathmann et al. teach compositions of homogeneous agarose beads and porous beads of 50-500 μm diameter containing pores of an average diameter

Art Unit: 1639

of 28 μm with embedded cells, particles, proteins, or polysaccharides wherein each bead is individually identifiable (please refer to the entire reference particularly the abstract; Figures 1 and 4; page 233, right column).

For present claims 38-39, Strathmann et al. teach functionalized sites with reactive groups (e.g. immobilization procedures; please refer to the entire reference particularly paragraph spanning pages 231-232; page 234, right column).

For present claim 40, Strathmann et al. teach agarose beads with pores in which bacteria cells are embedded and can be individually identified (please refer to the entire reference particularly Figure 4).

For present claim 42, Strathmann et al. teach three dimensional beads with three dimensional cells embedded (i.e. can be defined by x,y,z coordinates; please refer to the entire reference particularly Figure 4).

Therefore, the presently claimed invention is anticipated by the teachings of Strathmann et al.

19. Claims 32 and 38-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Grotli et al. U.S. Patent 6,642,334 (effective filing date of July 9, 2001).

The applied reference has a common inventor (i.e. Morten Meldal) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was

Art Unit: 1639

derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

For present claims 32 and 41, Grotli et al. teach compositions of beaded polyethylene glycol-based resins in silicone oil wherein the beads are individually identifiable and have sizes of about 0.01 to 5 mm, around 500 μm , around 300 μm with particles less than 30 μm (please refer to the entire specification particularly the abstract; Figures 1A, 1B, and 1C; columns 1-3, 5-6, 9-10; Experiments 2-4).

For present claims 38-39, Grotli et al. teach functionalization sites comprising reactive groups including hydroxyl groups, peptide with a proteolytic cleavage site, etc. (please refer to the entire specification particularly column 10, lines 7-23; Experiment 4).

For present claim 40, Grotli et al. teach ligands or bioactives attached to the beads including drugs, molecularly diverse compounds, etc. (please refer to the entire specification particularly the abstract; column 9, lines 30-67; column 10, lines 1-27; Experiment 4).

For present claim 42, Grotli et al. teach particles within the three dimensional beads (i.e. can be defined by x,y,z coordinates; please refer to the entire specification particularly Figures 1A, 1B, and 1C).

Therefore, the presently claimed invention is anticipated by the teachings of Grotli et al.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claims 32-33 and 38-42 are rejected under 35 U.S.C. 103(a) as being obvious over Grotli et al. U.S. Patent 6,642,334 (effective filing date of July 9, 2001) and Seul et al. U.S. Patent 7,156,315 (effective filing date of April 25, 1996).

The applied reference has a common inventor (i.e. Morten Meldal) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

For present claims 32 and 41, Grotli et al. teach compositions of beaded polyethylene glycol-based resins in silicone oil wherein the beads are individually identifiable and have sizes of about 0.01 to 5 mm, around 500 μm , around 300 μm with particles less than 30 μm (please refer to the entire specification particularly the abstract; Figures 1A, 1B, and 1C; columns 1-3, 5-6, 9-10; Experiments 2-4).

Art Unit: 1639

For present claims 38-39, Grotli et al. teach functionalization sites comprising reactive groups including hydroxyl groups, peptide with a proteolytic cleavage site, etc. (please refer to the entire specification particularly column 10, lines 7-23; Experiment 4).

For present claim 40, Grotli et al. teach ligands or bioactives attached to the beads including drugs, molecularly diverse compounds, etc. (please refer to the entire specification particularly the abstract; column 9, lines 30-67; column 10, lines 1-27; Experiment 4).

For present claim 42, Grotli et al. teach particles within the three dimensional beads (i.e. can be defined by x,y,z coordinates; please refer to the entire specification particularly Figures 1A, 1B, and 1C).

However, Grotli et al. only teach a composition with approximately 80 beads (i.e. not at least 100).

For present claim 33, Seul et al. teach arrays of beaded polymer matrixes comprising 100 beads (please refer to Figures 2A, 2B, 2C, 2D, 3c, 3d, 4A, 4B, 5, 7, 9a, 14a, 14b, 14c, 14d, 15a, 15b, 16-25a, 25c, 26b, 27-29; columns 2 and 6; paragraph spanning columns 16-17; Examples III-VII, IX-X; column 41, lines 48-57).

The claims would have been obvious because the substitution of one known element (i.e. composition of approximately 80 beads) for another (i.e. composition of 100 beads) would have yielded predictable results (i.e. ability to test addition ligands bound to the additional beads, etc.) to one of ordinary skill in the art at the time of the invention. See *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

Art Unit: 1639

improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 32 and 38-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-10 and 59 of copending Application No. 11/631,181. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention as claimed in U.S. application 11/631,181 are drawn to a composition of spatially encoded beads.

For present claims 32 and 41, U.S. application 11/631,181 claims a mcomposition comprising a plurality of spherical beads with a radiofrequency chip embedded wherein essentially each of said beads is individually identifiable (please refer to claim 3).

For present claims 38-40, U.S. application 11/631,181 claims hydrophilic moieties (i.e. functionalisation site), surface polyethers, surface polyvinyls, surface polyacrylates, surface polyacylamides polyacrylamides, surface polystyrenes, surface polycarbonates, surface polyesters, and surface polyamides (please refer to claims 4-6).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 32 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 94 and 96 of copending Application No. 10/566,757. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention as claimed in U.S. application 10/566,757 are drawn to a beaded polymer matrix comprising beads with a plurality of spatially immobilized particles.

For present claims 32 and 41, U.S. application 10/566,757 claims a beaded polymer matrix comprising beads with a plurality of spatially immobilized particles wherein each particle comprises at least one fluorescent dye compound and wherein each particle is individually detectable (please refer to claims 94 and 96).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Patent Examiner, Art Unit 1639

April 7, 2008